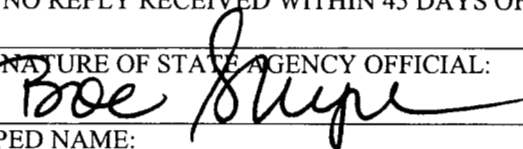



TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL		1. TRANSMITTAL NUMBER: 2004-011	2. STATE Florida
FOR: HEALTH CARE FINANCING ADMINISTRATION		3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
		4. PROPOSED EFFECTIVE DATE July 1, 2003	
TO: REGIONAL ADMINISTRATOR HEALTH CARE FINANCING ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES			
5. TYPE OF PLAN MATERIAL (Check One):			
<input type="checkbox"/> NEW STATE PLAN <input type="checkbox"/> AMENDMENT TO BE CONSIDERED AS NEW PLAN <input checked="" type="checkbox"/> AMENDMENT			
COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (Separate Transmittal for each amendment)			
6. FEDERAL STATUTE/REGULATION CITATION: 42 CFR 440.120		7. FEDERAL BUDGET IMPACT:	
		a. FFY 2004 \$0 \$(640,250.88)	
		b. FFY 2005 \$0 \$(933,695.76)	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Attachment 3.1-A, pages 46 and 46a Attachment 3.1-B, pages 45 and 45a		9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable): Attachment 3.1-A, pages 46 and 46a Attachment 3.1-B, pages 45 and 45a	
10. SUBJECT OF AMENDMENT: Value-Added Supplemental Rebate Agreements With Drug Manufacturers			
11. GOVERNOR'S REVIEW (Check One):			
<input type="checkbox"/> GOVERNOR'S OFFICE REPORTED NO COMMENT		<input checked="" type="checkbox"/> OTHER, AS SPECIFIED: Will forward when received.	
<input type="checkbox"/> COMMENTS OF GOVERNOR'S OFFICE ENCLOSED			
<input type="checkbox"/> NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL			
12. SIGNATURE OF STATE AGENCY OFFICIAL: 		16. RETURN TO:	
13. TYPED NAME: Mr. Bob Sharpe		Mr. Bob Sharpe	
14. TITLE: Deputy Secretary for Medicaid		Deputy Secretary for Medicaid	
15. DATE SUBMITTED: March 31, 2004		Agency for Health Care Administration	
		2727 Mahan Drive, Mail Stop #8	
		Tallahassee, FL 32308	
		Attention: Kay Newman	
FOR REGIONAL OFFICE USE ONLY			
17. DATE RECEIVED: March 31, 2004		18. DATE APPROVED: June 29, 2004	
PLAN APPROVED - ONE COPY ATTACHED			
19. EFFECTIVE DATE OF APPROVED MATERIAL: January 1, 2004		20. SIGNATURE OF REGIONAL OFFICIAL: 	
21. TYPED NAME: Renard L. Murray, D.M.		22. TITLE: Associate Regional Administrator	
		Division of Medicaid & Children's Health	
23. REMARKS:			
Approved with the following change to item 4: Changed from July 1, 2003 to January 1, 2004			
This change was authorized by the State Agency per e-mail on June 10, 2004			
Change to item #7 authorized by State Agency per e-mail dated June 22, 2004.			

Covered outpatient drugs are those produced by any manufacturer, which has entered into and complies with an agreement under Section 1927(a) of the Act, which are prescribed for a medically accepted indication. All Medicaid recipients 21 years of age and older will be limited to four brand-name drugs per month. There are no instances in which recipients under the age of 21 have system limitations placed on the number of prescriptions, brand or multi-source, they may receive. Generic drugs, insulin and diabetic supplies, contraceptives, mental health drugs, and anti-retroviral drugs are exempt from these limits. Based on the treatment needs of the Medicaid recipients, the agency may authorize exceptions to the brand-name-drug restriction. These exceptions will be based on prior consultation by the prescriber with the agency or agency contractor. Approved smoking cessation and nicotine replacement products are covered services. As provided by Section 1927(d)(2) of the Act, certain outpatient drugs may be excluded from coverage. Those excluded are DESI drugs; experimental drugs; anorectics (unless prescribed for an indication other than obesity); non-legend drugs (except insulin, aspirin, aluminum and calcium products used as phosphate binders, sodium chloride for specific medical indications, and OTC vaginal antifungals that have previously been legend drugs, when prescribed); and any drugs for which the manufacturer has not entered into rebate agreements with the Department of Health and Human Services, the Veteran's Administration and the Public Health Service. Cough and cold preparations are not covered services for recipients 21 years of age and older. Vitamin and mineral products are covered only under the following circumstances: prenatal vitamins; folic acid as a single entity; fluorinated pediatric vitamins; one vitamin or vitamin/mineral prescription monthly for a dialysis patient; and prescribed ferrous sulfate, gluconate, or fumarate for non-institutionalized patients. (Ferrous sulfate, gluconate, or fumarate is equally available as floor stock to institutionalized patients.) Non-Child Health Check-Up 221 recipients 21 years of age and older cannot receive immunizations, except for influenza and pneumococcal vaccines for institutionalized recipients. Drugs must be prescribed and dispensed in accordance with medically accepted indications for uses and dosages.

Drug Rebate Agreement: The state is in compliance with Section 1927 of the Act. Based on the requirements for Section 1927 of the Act, the state has the following policies for drug rebate agreements:

- The drug file permits coverage of participating manufacturers' drugs.
- Compliance with the reporting requirements for state utilization information and restrictions to coverage.
- A rebate agreement, Version 07/02/03, between the state and a drug manufacturer that is separate from the drug rebate agreements of Section 1927 is authorized by the Centers for Medicare and Medicaid Services. The agreement to be used between the State of Florida and drug manufacturers for supplemental rebates for drugs provided to the Medicaid population has been reviewed and authorized by the Centers for Medicare and Medicaid Services. The state reports rebates from separate agreements to the Secretary for Health and Human Services. The state will remit the federal portion of any state supplemental rebates collected.
- A value-added supplemental rebate agreement between the state and a drug manufacturer for drugs provided to the Medicaid population, submitted to CMS on March 31, 2004 and entitled "Services Agreement between Florida Agency for Health Care Administration and GlaxoSmithKline" has been authorized by CMS. The state reports rebates from this value-added agreement to the Secretary for Health and Human services. The state will remit the federal portion of any value-added supplemental rebates collected.
- Manufacturers are allowed to audit utilization data.
- The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification.
- Prior authorization programs provide for a 24-hour turn-around on prior authorization from receipt of request, and at least a 72-hour supply in emergency situations.

Amendment 2004-011
Effective 01/01/2004
Supersedes 2003-01
Approved 06/29/2004

PREScribed DRUGS:

Attachment 3.1-A

Preferred Drug List with Prior Authorization: In accordance with Florida Statute 409.91195 and pursuant to 42 U.S.C. s1396r-8, there is created a preferred drug list with prior authorization for drugs not included on the preferred drug list. The makeup and appointment authority for the Pharmaceutical and Therapeutic Committee is modified to comply with 42 U.S.C. s1396r-8.

Prior Authorization Requirements:

In accordance with Florida Statute 409.912, prior authorization requirements may be established for certain drug classes, particular drugs, or medically accepted indications for uses and doses.

State Supplemental Rebates:

Florida Statute 409.912 authorizes the state to negotiate supplemental rebates from manufacturers that are in addition to those required by Title XIX of the Social Security Act. The agreement to be used between the State of Florida and drug manufacturers for supplemental rebates for drugs provided to the Medicaid population has been reviewed and authorized by the Centers for Medicare and Medicaid Services.

State Value-Added Supplemental Rebates:

Florida Statute 409.912 authorizes the state to negotiate supplemental rebates that may include, at the state's discretion, cash rebates and other program benefits that offset a Medicaid expenditure. Such other program benefits may include, but are not limited to, disease management programs, drug product donation programs, drug utilization control programs, prescriber and beneficiary counseling and education, fraud and abuse initiatives, and other services or administrative investments with guaranteed savings to the Medicaid program. The value added supplemental rebate agreements are separate from the drug rebate agreements of Section 1927 and Version 7/2/03 of the supplemental rebate agreement, authorized by CMS.

Prescription Discount Programs: In accordance with Florida Statutes 409.9066, Medicare Prescription Discount Program, and as provider enrollment criteria are developed at the discretion of the Agency, it is required as a condition of Medicaid provider enrollment that Medicaid participating pharmacy providers give price discounts to Medicare recipients who are Florida residents.

Amendment 2004-011
Effective 01/01/2004
Supersedes 2003-01
Approved 06/29/2004

PRESCRIBED DRUGS:

Attachment 3.1-B

Preferred Drug List with Prior Authorization: In accordance with Florida Statute 409.91195 and pursuant to 42 U.S.C. s1396r-8, there is created a preferred drug list with prior authorization for drugs not included on the preferred drug list. The makeup and appointment authority for the Pharmaceutical and Therapeutic Committee is modified to comply with 42 U.S.C. s1396r-8.

Prior Authorization Requirements:

In accordance with Florida Statute 409.912, prior authorization requirements may be established for certain drug classes, particular drugs, or medically accepted indications for uses and doses.

State Supplemental Rebates:

Florida Statute 409.912 authorizes the state to negotiate supplemental rebates from manufacturers that are in addition to those required by Title XIX of the Social Security Act. The agreement to be used between the State of Florida and drug manufacturers for supplemental rebates for drugs provided to the Medicaid population has been reviewed and authorized by the Centers for Medicare and Medicaid Services.

State Value-Added Supplemental Rebates:

Florida Statute 409.912 authorizes the state to negotiate supplemental rebates that may include, at the state's discretion, cash rebates and other program benefits that offset a Medicaid expenditure. Such other program benefits may include, but are not limited to, disease management programs, drug product donation programs, drug utilization control programs, prescriber and beneficiary counseling and education, fraud and abuse initiatives, and other services or administrative investments with guaranteed savings to the Medicaid program. The value-added supplemental rebate agreements are separate from the drug rebate agreements of Section 1927 and Version 7/2/03 of the supplemental rebate agreement, authorized by CMS.

Prescription Discount Programs: In accordance with Florida Statutes 409.9066, Medicare Prescription Discount Program, and as provider enrollment criteria are developed at the discretion of the Agency, it is required as a condition of Medicaid provider enrollment that Medicaid participating pharmacy providers give price discounts to Medicare recipients who are Florida residents.

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